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EXAMINER

18M2/1030

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DATE MAILED: 10/30/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on July 10, 1997

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 (three) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 2, 3 and 5-12 is/are pending in the application.
Of the above, claim(s) 2, 3, 5 and 6 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 7-12 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 2, 3 and 5-12 are subject to restriction or election requirement.

**Application Papers** Substitute

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 Substitute
☐ Notice of Informal Patent Application, PTO-152

**--SEE OFFICE ACTION ON THE FOLLOWING PAGES--**



★ U.S. GPO: 1998-404-496/40517

## DETAILED ACTION

### *Response to Amendment*

1. Applicant's amendment filed July 10, 1997 has been entered and considered. Claims 1 and 4 have been canceled. New claims 7-12 have been entered. Claims 2, 3 and 5-12 are pending. Claims 2, 3, 5 and 6 remain withdrawn from consideration as being directed to a non-elected invention as described in the election with traverse in the previous Office Action of February 7, 1997.

### *Specification*

2. The Examiner acknowledges Applicant's amendments to the specification concerning trademarks.

3. The disclosure is again objected to because of the following informality: there is an undefined acronym "CTAB" on page 12, line 6.

Appropriate correction is required.

### *Objections/Rejections Withdrawn*

4. In light of their cancellation, the previous rejection of claims 1 and 4 under 35 U.S.C. 112, first paragraph, is withdrawn.

5. In light of their cancellation, the previous rejection of claims 1 and 4 under 35 U.S.C. 102(b) as being anticipated by GibcoBRL is withdrawn.

### *Claim Objections*

6. Claim 9 is objected to because of the following informality: there is a grammatical error in line 2 of the claim which recites "based on said enzymes substrate specificity" where the possessive form "enzyme's" appears to be required. Appropriate correction is required.

### *Claim Rejections - 35 U.S.C. § 112*

7. Claims 9 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 9 is drawn to encompass kits comprising enzymes selected based on their "substrate specificity for structures which are covalently attached to a functionality selected from" (emphasis added) various chemical moieties. While the specification at page 6, lines 9-13 (by actual line counting) describes enzymes that react with the chemical moieties recited in the claim, such a description does not support the scope of "specificity for structures which are covalently attached" to such moieties. Since there is no indication that the range of "specificity for [such] structures" was within the scope of the invention as conceived by Applicants at the time the

application was filed, the claim constitutes new matter which must be canceled in response to this Office Action.

Claim 11 is drawn to encompass kits comprising enzymes selected based on "molecular weight, isoelectric point, amino acid content and crystal structure." Despite a review of the specification, the Examiner is unable to locate support for the scope of selecting enzymes based on such criteria. Thus the claim constitutes new matter which must be canceled in response to this Office Action.

***Claim Rejections - 35 U.S.C. § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by GibcoBRL. Applicant's arguments with respect to the previous rejection under 35 U.S.C. 102(b) have been fully considered as they pertain the instant rejection, and they will be fully addressed immediately following a statement of the rejection.

GibcoBRL teach a kit for cDNA synthesis which comprises *E. coli* DNA ligase (a ligase), polymerase I (a transferase), and RNase H (a hydrolase); T4 DNA ligase (a ligase), DNA polymerase I (a transferase), and polynucleotide kinase (a transferase); and a reverse transcriptase

(a transferase). All of the above enzymes are recognized in the art as reacting with nucleic acid substrates that comprise the chemical moieties recited in the limitations of claim 8. Moreover, nucleic acids are known in the art to be chiral compounds and the above enzymes produce a specific enantiomeric product as recited in claim 10. Thus GibcoBRL anticipate the claims. The Examiner notes that the recitation in claim 7 that the kit is "for screening recombinant enzymes" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. See MPEP 2111.02. In the instant case, there are structural limitations in the claims that are able to stand alone, resulting in no patentable weight being accorded to the intended use in the preamble. Similarly, the recitations of the enzymes being selected based on "substrate specificity" (claim 9) and on "molecular weight, isoelectric point, amino acid content and crystal structure" (claim 11) impart no patentable weight or novelty since they only refer to methods of enzyme selection and hence are directed to methods of making of the claimed kits. Such phrasing results in a product-by-process limitation within the claims that does not affect the determination of patentability based on the claimed product itself. See MPEP 2113.

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Applicant argues that the reference teaches a kit containing purified enzymes while the claims are directed to kits containing compositions of enzymatic activities broadly

characterized; that the invention provides a starting point for the identification of novel enzymatic activities; that the invention is not intended to provide purified enzymes for the purpose of synthesizing cDNA; and that the reference does not teach each and every element of the claimed invention.

While the Examiner agrees that GibcoBRL teaches a kit containing purified enzymes, he notes that those enzymes have been characterized in the art according to the classifications recited in the claims. Moreover, and contrary to Applicant's assertion, the claims are directed to kits comprising "at least one protein" (see claim 7) or "at least two proteins" (see claim 12) rather than "compositions of enzymatic activities". Thus the reference anticipates the limitations of the claims.

As for Applicant's assertions that the invention provides a starting point for the further analysis and identification of novel enzymatic activities and that the intention was not to provide purified enzymes for synthesizing cDNA, the Examiner notes that as explained above, the intended use of a claimed product imparts no patentable weight where the structural limitations stand alone. In the instant case, the limitations of kits comprising enzymes having various activities are met by the reference.

For the reasons presented above, the limitations presented in claims 7-12 have been fully addressed and GibcoBRL anticipate the claims.

9. Claims 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim.

Boehringer Mannheim teach the sale of containers comprising a combination of hexokinase (a transferase) and glucose-6-phosphate dehydrogenase (an oxidoreductase). These enzymes are recognized in the art as reacting with carbohydrate substrates that comprising moieties recited in the limitations of claim 8. Moreover, hexose and glucose are known in the art to be chiral compounds and the above enzymes produce a specific enantiomeric product as recited in claim 10. Thus Boehringer Mannheim anticipate the claims. The Examiner notes that the preamble recitation in claim 7, the product by process limitations of claims 9 and 11, and Applicant's arguments have been addressed in the immediately preceding rejection.

***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications should be directed to Kawai Lau whose telephone number is 703-308-4209. The examiner can normally be reached Monday-Friday from 7 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 703-308-4216. The fax phone number for Official Papers to this Group is (703) 305-3014 or (703)308-4242. The fax phone number for Unofficial Papers to the Examiner is (703) 305-7401.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**robert.wax@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 703-308-0196.

Kawai Lau, Ph.D.
October 8, 1997

ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
GROUP 180